

REMARKS

With this response claims 170, 171, 175, 190-201, 203, 214-230, 232-235, 237, and 238 are under consideration. Claims 170, 224, 225 and 238 have been amended. Claim 231 has been cancelled. No new matter has been added.

Interview Summary

Applicant wishes to thank the Examiner for the telephonic interview conducted with Applicant's representative on February 5, 2004. During the interview, the outstanding rejection of claim 170 as indefinite under 35 U.S.C. 112 was discussed. Specifically the term "mutagenizing at least one member of the library" was discussed. The Examiner took the position that this language implied a possible selection step which made the claim indefinite. Applicant's position was that the language merely stated what was involved in mutagenesis of a library. The Examiner agreed that the process of mutagenizing a library required that at least one member of the library undergo a mutation, but maintained the position that the "at least one" language made the term indefinite. Alternative language in which the claim simply read "subjecting the library to mutagenesis" was discussed. Applicant's representative asked the Examiner if this language would be interpreted by the Examiner to mean that any number from one, up to and including all of the members of the library had undergone mutation. Examiner agreed that this would be the proper interpretation. Based on this understanding, Applicant agreed to amend the claim. A similar discussion was held involving the term "expressing the DNA molecules of the library." It was agreed that the proper interpretation of this claim is that "expressing the DNA molecules of the library" includes situations in which any number, from one, up to and including all members of the library are actually expressed.

Objection Under 37 C.F.R. 1.75

In the Office action, Applicant was advised that should claim 203 be found allowable, claim 231 would be objected to under 37 C.F.R. 1.75 as being a substantial duplicate thereof. With this response, Applicant has cancelled claim 231, thus obviating the basis for the objection.

Double Patenting Rejections

In the Office action, claims 170, 171, 175, 190-201, 203, 214-235, 237, and 238 were rejected on the basis of the judicially created doctrine of obviousness double patenting over U.S. Patent No. 5,939,250 in view of U.S. Patent No. 5,605,793. Applicant files herewith a terminal disclaimer in compliance with 37 C.F.R. 1.321(c) thus overcoming this rejection. The Commissioner is hereby authorized to charge Deposit Account No. 50-0661 the amount of \$55.00 as set forth in 37 C.F.R. 1.20(d).

In the Office action, claims 170, 171, 175, 190-201, 203, 214-235, 237, and 238 were rejected on the basis of the judicially created doctrine of obviousness double patenting over U.S. Patent No. 5,958,672 in view of U.S. Patent Nos. 5,316,935 and 5,605,793. Applicant files herewith a terminal disclaimer in compliance with 37 C.F.R. 1.321(c), thus overcoming this rejection. The Commissioner is hereby authorized to charge Deposit Account No. 50-0661 the amount of \$55.00 as set forth in 37 C.F.R. 1.20(d).

In the Office action claims, 175, 190-201, 203, 214-235, 237, and 238 were provisionally rejected on the basis of the judicially created doctrine of obviousness double patenting over U.S. Patent Application Serial No. 09/375,605 in light of U.S. Patent Nos. 5,316,935 and 5,605,793. Applicant files herewith a terminal disclaimer in compliance with 37 C.F.R. 1.321(c), thus overcoming this rejection. The Commissioner is hereby authorized to charge Deposit Account No. 50-0661 the amount of \$55.00 as set forth in 37 C.F.R. 1.20(d).

In light of the above, Applicant respectfully requests that all rejections based on obviousness double patenting be withdrawn.

Art-Based Rejections

Applicant acknowledges that as of the Office action of August 13, 2003 there are no pending rejections based on either 35 U.S.C. § 102 or 35 U.S.C. § 103.

Non Art-Based Rejections

Rejections Under 35 U.S.C. § 112, second paragraph

In the Office action of August 13, 2003, claims 170, 171, 175, 190-201, 203, 214-235, 237 and 238 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for

failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. “In rejecting a claim under the second paragraph of 35 U.S.C. 112, it is incumbent on the examiner to establish that one of ordinary skill in the pertinent art, when reading the claims in light of the supporting specification, would not have been able to ascertain with a reasonable degree of precision and particularity the particular area set out and circumscribed by the claims.” *Ex parte Wu*, 10 USPQ 2d, 2031, 2033 (BPAI 1989). Thus, the Patent Office has the burden of proof of showing that the claim language is indefinite to one skilled in the art. “[T]he definiteness of the language employed must be analyzed - not in a vacuum, but always in light of the teaching of the prior art and the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art.” *In re Moore*, 439 F.2d 1232, 1235, 169 USPQ 236, (CCPA 1971). “If the claims, read in light of the specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the [PTO] can demand no more. *Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613 (Fed. Cir. 1985).

The Office action alleges that (b) of claim 170 is confusing because it could have more than one meaning. Based on the meaning of the term “subjecting the library to mutagenesis” agreed on during the interview and set forth in the interview summary above, Applicant has amended (b) of claim 170. It is Applicant’s understanding that as amended, (b) of claim 170 is not considered indefinite by the Examiner and does not include selection.

The Office action further alleges that (c) of claim 170 renders the claim indefinite because “[i]t is unclear to this examiner which of the various libraries in the claim to which the applicant is referring.” Based on the meaning of the terms “expressing the DNA molecules of the library” and “subjecting the library to mutagenesis” agreed on during the interview and set forth in the interview summary above, Applicant has amended (c) claim 170. Applicant contends based on the interview with the Examiner that as amended, claim 170 does not include a selection step and therefore does not produce the various libraries which form the basis for the rejection. To further clarify, Applicant has amended claim 170 to specifically recite that the DNA molecules of the mutagenized library are expressed. In doing so, Applicant contends that the amendment merely makes explicit what one skilled in the art would have considered implicit in the claim as

originally filed. In view of the amendment, Applicant respectfully requests reconsideration and withdrawal of this rejection.

The Office action also alleges that (d) of claim 170 renders the claim indefinite because it is unclear to the examiner how the comparison can take place without a step to identify and characterize a protein having an activity of interest before the mutagenizing step. Applicant respectfully submits that the Office action does not present a prima facie case of indefiniteness. The test for indefiniteness is not whether the claim is unclear to the examiner, but rather, if one skilled in the art is able to ascertain the area set out and circumscribed by the claims. To meet its burden, the Patent Office must provide reasoning as to why one skilled in the art would find the claimed method indefinite (see *Ex parte Wu*, supra). It is well established that the Patent Office does not meet its burden of proof by simply stating its opinion that a claim is unpatentable. See *In re Sang Su Lee*, 227 F.3d 1338 (Fed. Cir. 2002); *In re Dembiczak*, 175 F.3d 994 (Fed. Cir. 1999). In addition, the step of identifying and characterizing a protein having activity prior to mutagenesis is not necessary to carry out the claimed method. Claim 170 states that proteins are screened to identify a protein having an improved activity of interest compared to the activity identified, not the protein identified, prior to mutagenesis. Thus, it is the activities that are compared, not the proteins. The Office action provides no reason why one skilled in the art would find it necessary to identify and characterize a protein to measure its activity. For example and without limitation, it is quite possible to measure enzymatic activity in a cell extract without any knowledge of the exact identity or specific characteristics of the enzyme responsible for the observed activity. The purpose of the claim as stated in the preamble is to find a protein with an improved activity, not to identify proteins prior to improvement. Thus, Applicant contends that the claim as submitted would be clear to one skilled in the art. For the reasons set forth above, Applicant respectfully requests reconsideration and withdrawal of this rejection.

In the Office action, claim 220 was rejected as indefinite for lack of antecedent basis. Specifically, the Office action alleges that first, there is no basis for insertion of nucleic acid clones and second, that the act of pooling nucleic acids is a selection process that negates the requirement that the nucleic acids of the library be obtained without selection. Applicant respectfully traverses this rejection.

As with other rejections based section 112, second paragraph, the test is whether the claim would be clear to one skilled in the art. “[T]he failure to provide explicit antecedent basis for terms does not always render a claim indefinite. If the scope of a claim would be reasonably ascertainable by those skilled in the art, then the claim is not indefinite.” MPEP § 2173.05(e) citing *Ex parte Porter*, 25 USPQ 2d, 1144, 1145, (BPAI 1992). As with other rejections based on indefiniteness, the Patent Office must provide reasons as to why one skilled in the art would find the rejected language indefinite. The Office Action provides no such reasons, but simply states a standard for determining if a claim meets the requirements of section 112, second paragraph. The Federal Circuit has stated that rote application of legal tests without providing reasons does not meet the Patent Office’s burden of proof (See, *In re Rouffet*, 149 F.3d 1350, 1358 (Fed. Cir. 1998) rote application of test of obviousness insufficient). Thus, Applicant respectfully submits that the Patent Office has failed to meet its burden to present a prima facie case of indefiniteness.

Moreover, Applicant submits that it is well known to those skilled in the art that insertion of nucleic acids into clones is inherent in library construction. The Examiner is directed to Appendix A which is an excerpt from the *Encyclopedia of Molecular Biology*, describing DNA libraries and vectors and in particular the text describing the insertion of nucleic acids into vectors to create the library. Thus, Applicant contends that it is reasonably ascertainable by those skilled in the art that construction of a library involves the insertion of nucleic acids into vectors, and that in the case of claim 220 the nucleic acids are pooled prior to insertion.

Claim 220 was also rejected on the basis that requirement that the nucleic acids be pooled negates the embodiment that the nucleic acids be obtained without selection. In examining claims, the Patent Office is required to give the words of a claim their ordinary meaning as they would be understood by one skilled in the art unless a different meaning is provided by the applicant. See *Jonsson v. Stanley Works*, 903 F.2d 812 (Fed. Cir. 1990); *In re Morris*, 127 F.3d 1048 (Fed. Cir. 1997). The ordinary meaning of “pool” as set forth in the Merriam-Webster unabridged dictionary is to “combine with others”. The same dictionary defines “select” as “to choose something from a number or group.” Copies of the definitions are supplied for the Examiner’s convenience as Appendices B and C, respectively. Based on the plain and ordinary meaning of “pool”, it would be clear to one of skill in the art that pooling of the nucleic acids is

not a form of selection, but rather the opposite since choosing from a group is the opposite of combining with others. Applicant respectfully submits that contrary to the assertion in the Office action there is no conflict between the term “pooled” in claim 220 and the term “without selection” in claim 170. For the reasons stated above, Applicant respectfully requests reconsideration and withdrawal of the rejection of claim 220.

In the Office action, claim 221 was also rejected on the basis that pooling directly negates the “without selection” embodiment of claim 170. For the reasons set forth in conjunction with claim 220, Applicant respectfully requests reconsideration and withdrawal of this rejection of claim 221.

In the Office action claims 224, 225 and 238 were rejected as being indefinite for the use of the term “detectable molecule.” Applicant contends that one skilled in the art would be able to ascertain with reasonable certainty the area set out and circumscribed by the claims. To speed prosecution, however, Applicant has amended claims 224, 225 and 238 to recite a detectable label. Applicant submits that this amendment does not provide an additional limitation of the claims. In light of this amendment, Applicant respectfully requests reconsideration and withdrawal of this rejection of claims 224, 225 and 238. Applicant notes that this is the only pending rejection of claim 238.

In the Office action, claim 232 was rejected as indefinite for the limitation “screen further desired activity.” The Office action contends the phrase is also confusing because the claim is drawn to a single protein. As stated above, in examining claims the Patent Office is required to give words and phrases their ordinary meaning. “Further” is defined as “going or extending beyond what exists: additional.” (Merriam-Webster Unabridged Dictionary, Appendix D). Thus, based on the plain meaning of the word further, claim 232 encompasses the situation where the library is screened for additional activity or activities. The Office action presents no reasons as to why one skilled in the art would not be able to ascertain the area set out and circumscribed by the claims and so fails to present a prima facie case of indefiniteness. The Patent Office itself appears to adopt claim construction set forth by the Applicant, since the Office action states that the limitation is confusing because the claim is drawn to a single protein, thus implying that the claim recites more than one activity. In support of this statement, the Office action cites the use of the phrase “a modified protein” in independent claim 170 from which claim 232 depends.

Applicant respectfully submits that the Patent Office's reliance on the phrase "a modified protein" to conclude that the claims are drawn to a single protein is improper. It is generally accepted in patent parlance that "a" can mean more than one. *North American Vaccine v. American Cyanamid Co.*, 7 F.3d 1571 (Fed. Cir. 1993); *AbTox Inc. v. Exitron Corp.*, 122 F.3d 1019 (Fed. Cir. 1997). The Office action points to nothing in the specification to indicate that the Applicant restricted his invention to a single activity or protein. Thus, absent evidence to the contrary, the claim is not limited to a single protein as asserted by the Patent Office. In light of the Office action's failure to set forth a prima facie case and the improper limitation of the claim to a single activity or protein, Applicant respectfully requests reconsideration and withdrawal of this rejection of claim 232.

In the Office action claim 233 was rejected as indefinite based on the phrase "a difference in the substrate before ...after contact." Once again, the Office action does not provide reasons why one skilled in the art would not be able to ascertain the area set out and circumscribed by the claims, but rather simply states that the claim is unclear to the examiner. Applicant wishes to again respectfully point out that rote application of the phrase "does not clearly set forth the metes and bounds of the patent protection desired" does not satisfy the Patent Office's burden of proof. As such, the Office action fails to set forth a prima facie case of indefiniteness.

Applicant contends that the meaning of the claim would be clear to one skilled in the art. The difference to which the claim refers is the difference in the substrate before and after contact with the clone or product encoded by the clone. As would be recognized by one of ordinary skill in the art, the exact difference would depend on the substrate and protein produced by the clone. Although this may encompass a wide variety of differences, it is well established patent law that "breath is not indefiniteness." *In re Gardner*, 427 F.2d, 786, 788 (CCPA 1970). For the reasons set forth above, Applicant respectfully requests reconsideration and withdrawal of this rejection of claim 233.

In the Office action, claims 171, 175, 190-201, 203, 214-219, 223, 226-231, 234, 235, and 237 were rejected because they depend on rejected claims. The arguments set forth above apply with equal force to these claims. Applicant therefore respectfully requests reconsideration and withdrawal of all rejections of claims 171, 175, 190-201, 203, 214-219, 223, 226-231, 234, 235, and 237.